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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,057	09/07/2004	Pierre Roy	079777-0564 (EGS-005)	8466
48329 7590 01/09/2008 FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 01/09/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/507,057		ROY ET AL.	
	Examiner		Art Unit	
	Christopher D. Koharski		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 10/17/2007 in which no claims were amended. Currently claims 1-21 are pending for examination in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-9, 11-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Matkovich (5,868,433) in view of Folden (5,221,267). Matkovich discloses a connector assembly (Figure 1), which comprises a first fitting (100) and second fitting (200) for liquid transfer. Two sets of deformable interlocking tabs (160 and 158 or 233 and 236) that irreversibly interlock with the second assembly (200) are present. A resilient lip (249, 154) and recess (Figure 1, 100) are present wherein the lip section is compressible (col 8, ln 58) between the first fitting (100). Matkovich discloses

a connection means with an element that is breakable (170) (Figure 1). Matkovich meets the claim limitations as described above except for a weakened area comprising a notch that is breakable in response to shear force (Figures 1-10, cols 1-2).

However, Folden teaches a breakable tubing coupling.

Regarding claims 1-6, 8-9, 11-16 and 18-21, Folden teaches a connection device between a reservoir (29) and medical device (22, 24) that comprises a weakened area comprising a continuous notch (38) located behind an annular ring (50) that is breakable in response to shear force (Figure 3).

At the time of the invention, it would have been obvious to add the weakened section of Folden to the modified device of Matkovich in order to allow for a quick disconnect of the connection without a knife or scissors. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Folden (cols 3-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matkovich in view of Folden (5,221,267).

The modified Matkovich discloses the claimed invention except for the taper angle of 6 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to put a taper of 6 degrees on the connector of Matkovich, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 103

Claim 17 is rejected under 35 U.S.C 103(a) as being unpatentable over Matkovich in view of Folden in further view of Huet (6,595,981). The modified Matkovich meets the claim limitations as described above except for non-return means.

However, Huet teaches an automatic-closing connector for connecting a liquid injector.

Regarding claim 17, Huet teaches a non-return means (11) capable of preventing fluid backflow after injection (Figure 1).

At the time of the invention, it would have been obvious to add the non-return means of Huet to the modified device of Matkovich in order to prevent fluid backflow through the system. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Huet (col In 25-45).

Response to Arguments

Applicant's arguments filed 10/17/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Matkovich and Folden et al. is not obvious and that the Matkovich reference teaches away from the disconnect feature of Folden et al.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that combination is proper that the addition the quick disconnect feature of Folden et al. to the system of Matkovich would be obvious given the motivation supplied by the reference and is also within knowledge base of a person of ordinary skill in the art. The Matkovich connector teaches a connector that maintains sterility, it is well know that components need to be separated at specific times and are not used indefinitely, although is advantageous to have connectors not disconnect before they are required to, it is however needed to have a disconnect feature for emergency circumstances or for interchange circumstances. Folden et al. provides a disconnect feature that is an active disconnect system and is provided in the tubing channel holder. Therefore this addition can be added to the system of Matkovich and still maintain the connector assembly of Matkovich without comprising the sterility and integrity of the connector as argued by Applicant's Representative. Examiner asserts that a person of ordinary skill has good reason to pursue the known option within his of

her technical grasp and the product is not of innovation but of ordinary skill and common sense.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

1/3/08



Christopher D. Koharski
AU 3763

